

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXXX

Petitioner

v

File No. 123569-001

Priority Health

Respondent

Issued and entered
this 6th day of January 2012
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On September 27, 2011, XXXXX, RN, authorized representative of XXXXX (Petitioner), filed a request with the Commissioner of Financial and Insurance Regulation for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Commissioner notified Priority Health of the external review and requested the information it used to make its final adverse determination. Priority Health furnished the information on September 28, 2011. After a preliminary review of the material submitted, the Commissioner accepted the request for external review on October 4, 2011. Priority Health submitted additional information on October 11, 2011.

This case involves medical issues. Therefore, the Commissioner assigned the matter to an independent review organization which submitted its recommendation on October 18, 2011.

II. FACTUAL BACKGROUND

The Petitioner is a member of Priority Health, a health maintenance organization. His group health care benefits are defined in the Priority Health *Certificate of Coverage* (the certificate) and its prescription drug rider (the rider).

The Petitioner has a diagnosis of progressing chronic obstructive pulmonary disease (COPD) and emphysema. There are also suggestions that he may have alpha-1 antitrypsin

deficiency disease, an inherited genetic disorder. His physician prescribed Prolastin infusion therapy to treat his condition and requested coverage. Priority Health denied the request on the basis that the Petitioner did not meet its criteria for coverage.

The Petitioner appealed the denial through Priority Health's internal grievance process and received its final adverse determination dated September 1, 2011.

III. ISSUE

Did Priority Health correctly deny coverage for Prolastin infusion therapy?

IV. ANALYSIS

Petitioner's Argument

In a letter dated September 22, 2011, submitted with the request for external review, the Petitioner's authorized representative wrote:

Alpha-I Antitrypsin Deficiency Disease is a genetic inherited disorder. Prolastin is a **life-sustaining** IV infusion biological product. It is FDA approved and has been used for treating Alpha-I Antitrypsin Deficiency for many years now. Although there is no cure, it is a very appropriate treatment for this incurable disease. This disease causes early onset bullous emphysema and rapid decline in FEV1 with progression of Panacinar Emphysema and the infusions are needed indefinitely. Prolastin will help stabilize or slow the progression of the disease. **If left untreated, disease progression will lead to lung transplant or an untimely death.** As noted in the Appeal to Priority Health, [the Petitioner] is a 55 yr. old male with a diagnosis of progressing COPD and emphysema. He was tested for Alpha-I Antitrypsin Deficiency and is a PiMZ with an AAT level of 77 mg/dL. Although this is considered to be border-line low (the normal range being 104-276 mg/dL.), his respiratory symptoms have worsened in the past several years. Phenotype MZ usually is not considered to be a positive combination for confirmation of Alpha-I Antitrypsin Deficiency but sometimes patients with more common genotype combinations (such as MZ) are diagnosed and need treatment if they are symptomatic and have a decreased AAT. While some are considered to be carriers, documentation of some of these patients shows that they go on to develop full-blown symptoms of the disease and become very ill, requiring augmentation therapy. There is evidence that sometimes the alpha-I antitrypsin produced is less than effective and sometimes the M Allele can be folded, giving a false reading as a normal allele. The main issue for these patients is respiratory decline as indicated by a compromised and deteriorating FEV1. [The Petitioner's] PFT shows significant airflow obstruction with an FEV1 of 34%.

The Petitioner believes the Prolastin infusion therapy is medically necessary to treat his condition and should be a covered prescription.

Respondent's Argument

In its final adverse determination of September 1, 2011, Priority Health explained its reason for denying the Petitioner's request to cover his Prolastin infusion therapy:

Uphold denial – requested coverage will not be provided as [the Petitioner] does not meet the required criteria for coverage of Prolastin. Specifically, authorization for Prolastin requires a diagnosis of alpha-1 proteinase deficiency with clinically evident emphysema, an FEV1 between 30-65% of predicted, a serum AAT level less than 11 micro mols (less than 60 mg/dL), and that you are a non-smoker. A review of the information submitted by [the Petitioner's] doctor indicates his AAT level is greater than 60 mg/dL.

Priority Health believes that its denial of coverage for Prolastin is appropriate because the Petitioner did not meet its criteria.

Commissioner's Review

The certificate excludes from coverage services and supplies that are not medically or clinically necessary. In addition, under Priority Health's formulary, selected injectable drugs in certain categories, such as Prolastin, require prior authorization. The prior authorization form requires the following criteria be met to certify coverage for Prolastin:

Patient must:

- have a diagnosis of congenital alpha1-antitrypsin deficiency **with** clinically evident emphysema
- have a predicted FEV1 value between 30 and 65%
- have a serum AAT level less than 11 µmol/L (less than 60 mg/dL)
- be a non-smoker

The question of whether the Petitioner met the criteria for coverage of Prolastin was presented to an independent medical review organization (IRO) for analysis, as required by section 11(6) of the Patient's Right to Independent Review Act. The IRO reviewer is board certified in internal and pulmonary medicine and has been in practice for more than 15 years. The IRO report contained the following analysis and conclusion:

The MAXIMUS physician consultant explained that the member has chronic obstructive pulmonary disease from smoking 1 ½ to 2 packs a day of cigarettes for 39 years. The MAXIMUS physician consultant also explained that the

[Petitioner's] phenotype is MZ and the alpha-1 antitrypsin level is 77 mg/dL. The MAXIMUS physician consultant stated that this does not meet criteria for medical necessity of treatment with Prolastin. The MAXIMUS physician consultant indicated that there is no objective documentation that infusions of Prolastin would improve the long term outcome of [the Petitioner]. [citation omitted]

Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Prolastin is not medically necessary for treatment of [the Petitioner's] condition.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO's analysis is based on experience, expertise and professional judgment, and the Commissioner can discern no reason why the recommendation should be rejected in this case.

The Commissioner finds that Priority Health's denial of coverage for Prolastin infusion therapy is consistent with the certificate, prior authorization criteria and the drug rider.

V. ORDER

The Commissioner upholds Priority Health's final adverse determination of September 1, 2011. Priority Health is not required to cover Prolastin infusion therapy for the treatment of Petitioner's condition.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

R. Kevin Clinton
Commissioner